REMARKS

A. Status of the Claims

Claims 13-15 and 18-22 were pending at the time of the Action. Claim 13 has been amended to recite a peptide comprising a sequence $KLKL_5KLK$ (SEQ ID NO:6) and to recite that the I-/U-ODN comprises oligo d(IC)13, I-ODN2, or I-ODN2b. Claim 20 has been amended to delete the sequence $KLKL_5KLK$ (SEQ ID NO:6). Claim 14 has been canceled. New claims 29 and 30 have been added. Support for these claims may be found in the specification at, for example, page 16.

B. The Rejections Under 35 U.S.C. § 103 (a) Are Overcome

The Action rejected claims 13-15, 18-19, and 21-22 as being obvious over Fritz *et al.* (WO 02/32451) in view of Egyed *et al.* (WO 01/93903). The Action found claim 20 patentable over Fritz in view of Egyed. Claim 20 was directed to a vaccine in which Peptide A was $KLKL_5KLK$ (SEQ ID NO:6) and the I-/U-ODN was oligo $d(IC)_{13}$ The Action asserted that only claim 20 was allowable because it was the only claim commensurate with the scope of the unexpected results reported in the specification (Action, p. 3). Although Applicants disagree with this assessment, current claim 13 has been amended to define the peptide as having the sequence $KLKL_5KLK$. In addition, claim 13 has been amended to recite that the I/U-ODN comprises oligo $d(IC)_{13}$, I-ODN2, and I-ODN2b. The specification demonstrated surprising results with each of these I-/U-ODNs. Thus, the unexpected results reported in the specification is commensurate with the scope of claim 13.

The study described in Example 1 of the present specification compared the immune responses induced by the commercially available flu vaccine Fluvirin alone and adjuvanted with $Al(OH)_3$ or various ODNs and/or cationic peptides. Example 1 of the specification, illustrated by FIG. 1, demonstrated that the combination of $KLKL_5KLK$ and several I-/U-ODNs provided a

many-fold increase in the induction of an antigen-specific immune response humoral type 1 responses (IgG2b) as compared to the humoral type 1 responses (IgG2b) induced by Fluvirin or Fluvirin adjuvanted with $Al(OH)_3$, an I/U-ODN, or $KLKL_5KLK$ alone. As mentioned above, the I/U-ODNs used in this study were oligo $d(IC)_{13}$, I-ODN2, and I-ODN2b. In view of the low IgG2b titers achieved with Fluvirin or Fluvirin adjuvanted with $Al(OH)_3$, an I-/U-ODN, or a $KLKL_5KLK$ alone, the high IgG2b titer achieved when Fluvirin was administered with both $KLKL_5KLK$ and oligo $d(IC)_{13}$, I-ODN2, or I-ODN2b was surprising.

In addition, the potent immune response induced by the combination of $KLKL_5KLK$ and oligo $d(IC)_{13}$ with the commercially available flu vaccines Fluvirin and Agrippal S1 was demonstrated in Examples 2-4. These studies showed, for example, that the flu vaccine Agrippal S1 adjuvanted with $KLKL_5KLK$ and oligo $d(IC)_{13}$ induced synergistically stronger cellular and humoral immune responses than Agrippal S1 alone (Example 3). Accordingly, the data in the specification demonstrate that the elements recited in the currently claimed vaccine work together in an unexpected and fruitful manner, which is evidence that the current claims are non-obvious. Applicants, therefore, request the withdrawal of this rejection.

C. Double Patenting

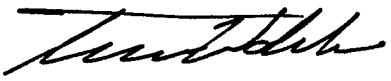
The Action raises several obviousness-type double patenting rejections. Claims 13-15, 18-19, and 21-22 are provisionally rejected for obviousness-type double patenting over claim 39 of co-pending U.S. Application 10/399,442. Claims 13-15, 18-19, and 21-22 are provisionally rejected for obviousness-type double patenting over claim 69 of co-pending U.S. Application 10/478,771. Claims 13-15, 18-19, and 21-22 are provisionally rejected for obviousness-type double patenting over claims 42 and 50 of co-pending U.S. Application 10/297,555. Claims 13-15, 18-19, and 21-22 are rejected for obviousness-type double patenting over claim 1 of U.S. Patent 7,148,191. Applicants traverse these rejections.

None of the claims of the co-pending applications nor the '191 patent render obvious the vaccine recited in the current claims. Current claim 13 is directed to a vaccine for preventing infections with influenza virus comprising: an influenza virus antigen; a peptide (Peptide A) comprising a sequence $KLKL_5KLK$ (SEQ ID NO:6); and an immunostimulatory oligodeoxynucleic acid molecule (I-/U-ODN), wherein the I-/U-ODN comprises oligo d(IC)13, I-ODN2, or I-ODN2b. A vaccine comprising these particular elements is not specifically disclosed in these references. As discussed in the preceding section, the working examples in the present specification demonstrate that the combination of an influenza virus antigen, $KLKL_5KLK$, and oligo d(IC)13, I-ODN2, or I-ODN2b was surprisingly effective at inducing immune responses. The fact that claim 20 was not included in any of these rejections indicates that the Examiner agrees that the surprising results disclosed in the specification show that the current claims are patentable over these references. Applicants, therefore, respectfully request the withdrawal of these rejections.

D. Conclusion

Applicants believe this paper to be a full and complete response to the Office Action dated January 6, 2009. Applicants respectfully request favorable consideration of this case in view of the above comments and amendments. Should the Examiner have any questions, comments, or suggestions relating to this case, the Examiner is invited to contact the undersigned Applicants' representative at 512/536-5654.

Respectfully submitted,



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